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Dated: April 21, 2000.

John L. Williams,

Director, Procurement and Grants Office Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1256]

Over-the-Counter Drug Products; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing about the agency's approach to regulating over-the-counter (OTC) drug products. The purpose of the hearing is to solicit information from, and the views of, interested persons, including scientists, professional groups, and consumers. FDA intends to elicit comment on general issues regarding the status of OTC drug products, including the criteria the agency should consider in rendering decisions on OTC availability of drugs, the classes of products, if any, that are not currently available OTC that should or should not be available OTC, how FDA can be assured that consumers understand the issues relating to OTC availability of drug products, how rational treatment decisions are affected by coexisting prescription and OTC therapies for a given disease, whether the current structure for marketing OTC products in the United States is adequate, and FDA's role in switching products from prescription to OTC status.

DATES: The public hearing will be held on Wednesday, June 28, and Thursday, June 29, 2000, from 8:30 a.m. to 4:30 p.m. Submit written notices of participation and comments for consideration at the hearing by June 2, 2000. Written comments will be accepted after the hearing until August 25, 2000.

ADDRESSES: The public hearing will be held at the Gaithersburg Holiday Inn, 2 Montgomery Village Ave., Gaithersburg, MD 20879. Submit written notices of participation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; email: FDADockets@oc.fda.gov; or through the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. Submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; email: FDADockets@oc.fda.gov; or through the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above) and on the Internet at http://www.fda.gov/ohrms/dockets.

FOR FURTHER INFORMATION CONTACT: Patricia L. DeSantis, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, e-mail: desantis@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA regulates all prescription and OTC drug products marketed in the United States. Section 503(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)) describes the criteria for determining whether a drug product is subject to prescription classification. Under section 503(b)(1) of the act, a drug requires a prescription if:

> (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
>
> (B) [it] is limited by an approved application under section 505 [of the act] to use under the professional supervision of a practitioner licensed by law to administer such drug.

All drug products not meeting the above criteria may be sold OTC.

In 1972, FDA initiated rulemaking procedures (the OTC Drug Review) to determine which OTC drugs can be generally recognized among qualified experts as safe and effective and not misbranded under prescribed, recommended, or suggested conditions of use. Through the OTC Drug Review, FDA establishes monographs for classes of OTC drug products (*e.g.*, antacids, skin protectants) that are found to be generally recognized as safe and effective and not misbranded when the products contain the ingredients and are labeled according to the monograph. OTC drug monographs describe the active ingredients, amount of drug, formulation, labeling, and other general requirements for drugs to be lawfully sold OTC.

The regulations for the OTC Drug Review are found in part 330 (21 CFR part 330) and the monographs are in 21 CFR parts 331 through 358. The regulations set forth standards for safety, effectiveness, benefit-to-risk considerations, and labeling of OTC drug products.

The standards for safety, effectiveness, and labeling for OTC products are described in § 330.10(a)(4). Safety for OTC use means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use, as well as low potential for harm which may result from abuse under conditions of widespread availability. Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. The benefit-to-risk ratio of a drug must be considered in determining both safety and effectiveness.

The labeling of OTC drug products must be clear and truthful in all respects and may not be false or misleading in any particular. The labeling must state: (1) The intended uses and results of product use; (2) the adequate directions for proper use; and (3) the warnings against unsafe use, side effects, and adverse reactions in terms that render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use (§ 330.10(a)(4)(v)).

During the course of the OTC Drug Review, advisory review panels of nongovernment experts evaluated the various classes of OTC drug products and recommended that a number of drugs be switched from prescription to OTC status. FDA acted on these recommendations and switched a number of products to OTC status, including antihistamines (*e.g.*, diphenhydramine hydrochloride (HCl), doxylamine succinate), topical nasal decongestants (*e.g.*, oxymetazoline HCl, xylometazoline HCl), topical hydrocortisone, topical antifungals (*e.g.*, haloprogin, miconazole nitrate), an anthelmintic (pyrantel pamoate), an oral anesthetic (dyclonine HCl), and various fluoride dental rinses.

FDA has also approved the switch of a number of drugs from prescription to OTC status under new drug applications. These include an antidiarrheal (loperamide), topical antifungals (*e.g.*, clotrimazole, terbinafine HCl), antihistamines (*e.g.*,